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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,590	04/08/2004	Paul Albert Sagel	9031R	8118
27752 7590 01/29/2009 THE PROCTER & GAMBLE COMPANY Global Legal Department - IP Sycamore Building - 4th Floor 299 East Sixth Street CINCINNATI, OH 45202				
EXAMINER				
ROBERTS, LEZAH				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
01/29/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/820,590

**Applicant(s)**

SAGEL ET AL.

**Examiner**

LEZAH W. ROBERTS

**Art Unit**

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-12 and 17-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-12 and 17-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed October 27, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claims*

#### **Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17, 18 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claim 22 recites the limitation "less than about." The term "less than" delineates only numerical values more than the recited value where the term "about" may be less than or more than the recited value. Because of the conflict of terms, it is unclear which term is limiting. See also MPEP 2173.05(b) (citing Amgen v. Chugai, 18 USPQ2d 1016 (Fed. Cir. 1991), in which the phrase "at least about" was held indefinite).

2) Claims 17 and 18 recite the phrases "substantially coextensive" and "substantially water impermeable" respectively. The claims are indefinite insofar as it cannot be determined from the instant disclosure or instant claims the degree of coextension or water impermeability is encompassed by the term "substantially".

**Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)**

1) Claims 1-3, 5-8, 11-12, 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godbey et al (US 2002/0187181) in view of Chang et al. (US 2003/0194382) and Sagel et al. (US 5,891,453).

Godbey et al. disclose delivery systems comprising a water-soluble polymeric carrier, an adhesive, one or more active agents and a support layer. The active agent includes whitening agents such as hydrogen peroxide (paragraph 0051) and may be incorporated into either one or both of the carrier and the adhesive compositions (paragraph 0008). The polymers that may be used as carriers include cold water-soluble polymers such as polyvinyl alcohol, which is the one of the preferred polymers, polyoxyalkylenes, and mixtures thereof. The advantage of using polymers of polyvinyl alcohols to prepare the carrier film is that the film may, as a result of its low oxygen permeability, provide protection to oxygen sensitive materials (paragraph 0025). The polyvinyl alcohol used in the examples was 87% hydrolyzed, encompassing claim 7, and may comprise 30 to 35% of the compositions. Plasticizers that may be used include polyethylene glycol, water and mixtures and comprise from 1 to 50% of the carrier. Plasticizers are used to form films with reduced brittleness. The carriers are cast into

films (paragraph 0025) encompassing claim 23. The adhesive compositions also include cold water-soluble polymers, such as poly(ethylene oxide) (paragraph 0036), and the polymers may be an uncross-linked polymer or mixture of polymers with an overall number average molecular weight between 10,000 and 100,000 Daltons. Such polymers provide a good balance of cohesive strength and water-solubility. The adhesive polymer comprises about 10 to about 60 weight percent of the adhesive composition, encompassing claim 2. Plasticizers comprise up to 80% of the adhesive compositions. The amount of water used in the adhesive compositions comprises up to 60% of the adhesive (paragraph 0041). It can be concluded that up to 60% water and amount of plasticizer is in the final product and not just the initial mixture because the components were disclosed as being in the compositions and not only being indicated as being used to make the compositions. The devices are 75 micrometers thick (paragraph 0068). The reference differs from the instant claims insofar as it does not disclose a layer comprising a combination of polyvinyl alcohol and polyethylene oxide or that teeth whitening devices were packaged.

Chang et al. disclose whitening patches comprising hydrogen peroxide. The compositions comprise polymers such as polyethylene oxide and polyvinyl alcohol (paragraph 0037). Polyethylene oxide has good compatibility with peroxide (paragraph 0041). The patches also comprise a backing layer (see Abstract). The reference differs from the instant claims insofar as it does not disclose the patches comprise water or are in a package.

Sagel et al. disclose systems for delivering whitening substances. The systems comprise strips coated with a whitening composition or substance. The compositions comprise whitening agents such as hydrogen peroxide and the amount of whitening agent in the compositions ranges from 0.01% to about 40% by weight of the substance. Water is also included in the compositions and comprises 0.1% to 95% by weight of the substance. The amount of substance applied on the strip is less than 0.2 grams/cm<sup>2</sup> (200 mm/cm<sup>2</sup>). The amount of substance applied to the strip of material or teeth will depend upon the size and capacity of the piece of material, concentration of the active, and the desired benefit (col. 7, lines 47-56). The strip of material may comprise materials such as polymers, natural and synthetic wovens, non-wovens, foil, paper, rubber, and combinations thereof. This is interpreted to encompass the recitation of holes in claims 20 and 21. Strips with holes also are interpreted to encompass discontinuous backing layers. The strip is less than 1 mm thick (col. 5, lines 58-65). The strip is covered with a release liner (col. 9, lines 56-65). The mention of the release liner leads one to believe the strips are packaged products, therefore encompassing the instant claims.

The reference differs from the instant claims insofar as it does not disclose a mixture of polyvinyl alcohol and polyethylene oxide as a gelling agent to use with the whitening agent.

It would have been obvious to one of ordinary skill in the art to have used polyethylene oxide as the polyoxyalkylene used in the carriers of Godby et al. motivated

by the desire to use a polymer that has good stability with peroxide as disclosed by Chang et al.

It would also have been obvious to one of ordinary skill in the art to have packaged the compositions of Godbey et al. and Chang et al. motivated by the desire to protect the delivery systems, as disclosed by the Sagel et al.

2) Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godbey et al (US 2002/0187181) in view of Chang et al. (US 2003/0194382) and Sagel et al. (US 5,891,453) in further view of Xu et al. (US 2002/0187111).

The primary and secondary references, Godbey et al., Sagel et al. and Chang et al., are discussed above. The references differ from the instant claims insofar as they do not disclose the molecular weights of the polyethylene oxide polymers that may be used in the whitening compositions.

Xu et al. teach whitening strips comprising polyethylene oxide. The whitening agents include hydrogen peroxide (paragraph 0011). The ethylene oxide polymer comprises 50 to 95% of the composition (paragraph 0012). The polymer is hydratable and varying the properties of the polymer can control the release of the whitening agent. Varying film thickness and using a mixture of different molecular weight polyethylene oxide polymers (100,000 –1,500,000 Daltons) varies the properties of the films (paragraph 0008-0010). Mixtures of polymers with different molecular weights are also disclosed by the primary reference. The strips are packaged in a suitable container

Art Unit: 1612

(paragraph 0022). The reference differs from the instant claims insofar as it does not disclose a second polymer such as polyvinyl alcohol.

It would have been obvious to one of ordinary skill in the art to have used the polyethylene oxides of different molecular weights and mixtures as the polyoxyalkylenes in the compositions of Godbey et al., Sagel et al. and Chang et al., motivated by the desire to make a whitening composition that provides a good balance of cohesive strength, is hydratable and has the desired rate of release of a whitening agent, as disclosed by Xu et al.

**Obvious-Type Double Patenting (Previous Rejection)**

Claims 1-12, 17, 18 and 23 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/936,756. The rejection is maintained.

Applicant does not appear to address the rejection therefore the rejection is maintained.

Claims 1-3, 5-12 and 17-23 are rejected.

No claims allowed.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612